

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Counter Terrorism Products Regulated by the Center for Biologics
Evaluation and Research: Effective Strategies to Assist in Product
Development; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Counter Terrorism Products Regulated by the Center for Biologics Evaluation and Research: Effective Strategies to Assist in Product Development." The purpose of the public workshop is to provide a forum for discussing strategies to assist in the effective development of products regulated by the Center for Biologics Evaluation and Research (CBER) that may be used in counter terrorism efforts (e.g., vaccines, blood and blood products including immunoglobulins, gene therapies, and human cellular and tissue-based products).

Date and Time: The workshop will be held on October 23, 2003, from 8:30 a.m. to 5 p.m., and on October 24, 2003, from 8:30 a.m. to 5 p.m.

Location: The workshop will be held at the Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD.

Contact Person: Gloria Blankenship, CBER (HFM-49), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-2000, FAX 301-827-3079, e-mail: Blankenship@cber.fda.gov.

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Certifier Cr. Henley

Registration: Mail, e-mail, or fax your registration information (including name, professional degree, title, e-mail address, firm name, address, telephone, and fax number) to Gloria Blankenship, (see *Contact Person*) by October 10, 2003. There is no registration fee for the public workshop. Because seating is limited, we recommend early registration. There will be no onsite registration.

If you need special accommodations due to a disability, please contact Gloria Blankenship (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The purpose of this public workshop is to provide a forum for sharing information and strategies to assist in the efficient and successful development of products regulated by CBER and used for counter terrorism efforts. CBER is interested in promoting a discussion of issues related to the development of counter terrorism products, including manufacturing and clinical issues, and other relevant issues. The workshop is intended to help sponsors address commonly asked questions and avoid common misunderstandings and to provide practical information on successful product development strategies.

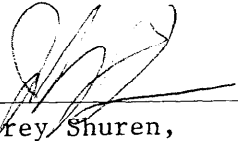
FDA invites participants to submit issues for discussion prior to the workshop. There will be an opportunity to raise additional questions and issues for discussion at the meeting. Mail or fax your issues and questions to Gloria Blankenship (see *Contact Person*) by October 10, 2003.

FDA will post on CBER's Web site (<http://www.fda.gov/cber/>) the agenda for this meeting, when finalized.

Transcripts: Please note that transcripts of the meeting will not be prepared.

Dated: 9/17/03
September 17, 2003.

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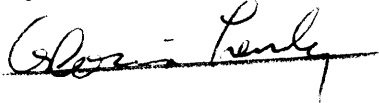


Jeffrey Shuren,
Assistant Commissioner for Policy.

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Gloria Penley